

**K191654 SILICONE Personal Lubricant**Apr 14, 2020  
299 days to decisionK191654 · Product code: **NUC** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k191654/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Jun 20, 2019
Decision date	Apr 14, 2020
Days to decision	299 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bath Concept Cosmetics (Dongguan) Co., Ltd.</b>
Location	Dongguan, CN
Contact	Jack Yin
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Rglm Consulting, LLC</b>
Contact	Wei Zhang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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